K003788

MAY 3 0 2001

510(K) Summary

SPONSOR:

Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700
Contact: Thomas M. Maguire

DEVICE NAME: Synthes Resorbable Meshes and Sheets

CLASSIFICATION: Class II, 21 CFR 888.3030: Single/multiple component bone fixation appliances and accessories.

PREDICATE DEVICE: MacroPoreOS Protective Sheet

INTENDED USE: Synthes resorbable meshes and sheets are intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. Synthes resorbable meshes and sheets are also indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, Synthes resorbable meshes and sheets are intended to maintain the relative position of weak bony tissue in trauma and reconstructive procedures involving:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), Synthes resorbable meshes and sheets are intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive procedures involving:

- Tumor resections where bone stability has not been compromised
- Iliac crest harvests

These devices are not intended for use in the spine. The devices are not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

MATERIAL: Poly(L/DL-lactide)

K003788

DEVICE DESCRIPTION:

Synthes resorbable meshes and sheets are available in a range of sizes from 20 x 20 mm to 125 x 125 mm. The thickness of the mesh plates and sheets range from 0.50 mm to 2.0 mm. Pore sizes of the mesh plates range from 1.7 mm to 3.5 mm in diameter.

Synthes resorbable meshes and sheets can be cut to a desired shape or size using scissors or plate cutters. When heated, for example by the use of sterile hot water or hot air, the resorbable meshes and sheets are malleable and can be rolled into a tubular form, or contoured three dimensionally to match anatomical structures. Testing has shown that the bending strength and bending stiffness of the resorbable meshes and sheets does not change after shaping up to ten times. The resorbable meshes and sheets are fixed to the bone using Synthes resorbable screws or resorbable tacks. The resorbable meshes and sheets may be used, as indicated, either alone or in conjunction with internal fixation devices (e.g. metallic plates and screws) that serve to further stabilize the treatment area

Researchers have shown that polymer solutions to bone graft containment offer several benefits including: optimizing the contact between the soft tissues and bone graft to avoid excessive graft resorption and maintaining the graft in the required location.[1]

It has been determined that resorbable meshes and sheets, up to a total implant weight of 100 grams can be safely used in a single surgery without compromising the ability of the material to be safely metabolized.

Accelerated aging testing of the Synthes Resorbable Meshes and Sheets has been performed that shows significant retention of device rigidity and strength during the 12 week healing period.

[1] Gugala Z, Gogolewski S. Regeneration of segmental diaphyseal defects in sheep tibiae using resorbable polymeric membranes: a preliminary study. *Journal of Orthopaedic Trauma* 1999; Vol. 13, No. 3, pp 187-195

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Mr. Thomas M. Maguire
Project Leader, Regulatory Affairs
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K003788
Trade/Device Name: Synthes Resorbable Meshes and Sheets
Regulation Number: 888.3030
Regulatory Class: II
Product Code: HRS, MAI
Dated: March 5, 2001
Received: March 7, 2001

Dear Mr. Maguire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use Statement

510(k) Number (if known): K003788

Device Name: Synthes (USA) Resorbable Meshes and Sheets

Indications/Contraindications:

Synthes resorbable meshes and sheets are intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. Synthes resorbable meshes and sheets are also indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, the Synthes resorbable meshes and sheets are intended to maintain the relative position of weak bony tissue in trauma and reconstructive procedures involving:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), Synthes resorbable meshes and sheets are intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive procedures involving:

- Tumor resections where bone stability has not been compromised
- Iliac crest harvests

These devices are not intended for use in the spine. The devices are not intended for load bearing indications unless used in conjunction with traditional rigid fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Synthes (USA)
Resorbable Meshes and Sheets

510(k) Number Confidential K003788